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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/638,172	08/07/2003	Wayne A. Border	66821-236	3802

7590 12/03/2004

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EXAMINER
GAMBEL, PHILLIP

ART UNIT	PAPER NUMBER
1644	

DATE MAILED: 12/03/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/638,172	BORDER ET AL.	
	Examiner	Art Unit	
	Phillip Gambel	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 August 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-18* is/are pending in the application.

4a) Of the above claim(s) *3,4,8,9,11,12 and 16-18* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1, 2, 5-7, 10, 13-15* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1)☒ Notice of References Cited (PTO-892)
2)☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3)☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4)☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5)☐ Notice of Informal Patent Application (PTO-152)
6)☐ Other: _____.

DETAILED ACTION

1. Applicant's election with traverse of Group I (claims 1, 2, 5-7, 10 and 13-15) and the species glomerulonephritis in Response to Restriction Requirement, filed 8/18/04, is acknowledged.

The traversal is on the ground(s) that Groups I and IV have extensive overlap between the methods for treating pathologies and the corresponding diagnostic methods, and therefore the examiner will not be seriously burdened to search and examine both Groups. This is not found persuasive because of the inventions must be independent (see MPEP 802.01, 806.04, 808.01) or distinct as claimed (see MPEP 806.05-806.05(I))) for the reasons of record set forth in the Restriction Requirement. Inventions I and IV are different methods of use, which require different ingredients, process steps and endpoints. Also, the inventions require non-coextensive searches whether or not the classifications alone are coextensive. Therefore, they are patentably distinct.

The requirement is still deemed proper and is therefore made FINAL.

Claims 1-2, 5-7,10, and 13-15 as they read on methods of treating glomerulonephritis with anti-TGF-β antibodies are under consideration in the instant application.

Claims 3-4, 8-9, 11-12 and 16-18 have been withdrawn from further consideration by the examiner, 37 C.F.R. § 1.142(b) as being drawn to a nonelected inventions.

It is noted that applicant has indicated that claim 10 has been (Withdrawn), however claim 10, which depends on claim 6, does read on the elected invention ("tissue is comprised of cells selected from the group of kidney as it reads on glomerulonephritis). Therefore, applicant should review the status of the pending claims.

2. If applicant desires priority under 35 U.S.C. 120 based upon a previously filed copending application, specific reference to the earlier filed application must be made in the instant application. This should appear as the first sentence of the specification following the title, preferably as a separate paragraph. The status of nonprovisional parent application(s) (whether patented or abandoned) should also be included. If a parent application has become a patent, the expression "now Patent No._____" should follow the filing date of the parent application. If a parent application has become abandoned, the expression "now abandoned" should follow the filing date of the parent application.

Applicant should amend the first line of the specification to update the status of the priority documents.

3. Applicant is reminded that affidavits and declarations, such as those under 37 C.F.R. § 1.131 and 37 C.F.R. § 1.132, filed during prosecution of the parent application do not automatically become a part of this application. Where it is desired to rely on an earlier filed affidavit, the applicant should make the remarks of record in the later application and include a copy of the original affidavit filed in the parent application.

4. The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed. Applicant should restrict the title to the claimed invention

5. The application is required to be reviewed and all spelling, TRADEMARKS, and like errors corrected.

Trademarks should be capitalized or accompanied by the ™ or ® symbol wherever they appear and be accompanied by the generic terminology. Although the use of trademarks is permissible in patent applications, the proprietary nature of the trademarks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

Appropriate corrections are required

6. No Information Disclosure Statement has been filed with the instant application.

7. Claim 6-7 and 10 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 6-7 and 10 are indefinite in the recitation of "suppressing the activity of TGF-β in antibodies" because the recitation of "in antibodies" does not make sense.

Applicant should amend the claims to particularly point out and distinctly claim the claimed subject matter to resolve this ambiguity.

Applicant should specifically point out the support for any amendments made to the disclosure. See MPEP 714.02 and 2163.06

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office Action:

A person shall be entitled to a patent unless --

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office Action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

9. Claims 1-2, 5-7, 10, 13 and 15 are rejected under 35 U.S.C. § 102(e) as being anticipated by Dasch et al. (U.S. Patent No. 5,772,998) (see entire document).

Dasch et al. teach the use of TGF-β-specific antibodies to neutralize the effects of TGF-β, including lung fibrosis, liver cirrhosis fibrotic skin disorders and scarring (see entire document, including columns 5-6 and the Claims). Applicant is reminded that no more of the reference is required than that it sets forth the substance of the invention. The claimed functional limitations would be inherent properties of the referenced methods to treat various fibrotic conditions with the same neutralizing TGF-β-specific antibodies encompassed by the claimed methods.

Although the reference is silent about "decreasing the produciotn of a proteoglycan by a cell wherein the proteoglycan is selected from the group consisting of biglycan and decorin, it does not appear that the claim language or limitations result in a manipulative difference in the method steps when compared to the prior art disclosure. See Bristol-Myers Squibb Company v. Ben Venue Laboratories 58 USPQ2d 1508 (CAFC 2001). "{i}t is a general rule that merely discovering and claiming a new benefit of an old process cannot render the process again patentable." In re Woodruff, 16 USPQ2d 1934, 1936 (Fed. Cir. 1990). The mechanism of action does not have a bearing on the patentability of the invention if the invention was already known or obvious. Mere recognition of latent properties in the prior art does not render nonobvious an otherwise known invention. In re Wiseman, 201 USPQ 658 (CCPA 1979). Granting a patent on the discovery of an unknown but inherent function would remove from the public that which is in the public domain by virtue of its inclusion in, or obviousness from, the prior art. In re Baxter Travenol Labs, 21 USPQ2d 1281 (Fed. Cir. 1991). See MPEP 2145.

10. Claims 1-2, 5-7,10, and 13-15 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Dasch et al. (U.S. Patent No. 5,772,998) in view of Ruoslahti et al. (U.S. Patent No. 5,583,103) AND/OR Bassols et al. (J.Biol. Chem. 263: 3039-3045, 1988).

Dasch et al. teach the use of TGF-β-specific antibodies to neutralize the effects of TGF-β, including lung fibrosis, liver cirrhosis fibrotic skin disorders and scarring (see entire document, including columns 5-6 and the Claims).

Dasch et al. differs from the claimed methods by not disclosing that TGF-β was responsible, at least in part, for glomerulonephritis.

Ruoslahti et al. teach that it was known that excessive accumulation of extracellular matrix in glomerulonephritis was a diseases with a detrimental involvement of TGF-β (see column 2, paragraph 1) and that by treating TGF-β regulated activities, one treats certain pathologies including fibrotic disease and glomerulonephritis (see columns 5-6, overlapping paragraph). Further, Ruoslahti et al. Teach that TGF-β -specific antibodies were able to inhibit the activity of TGF-β (see column 13)

Bassols et al. teach TGF-β regulates the expression of the extracellular matrix chondrotin/dermatan sulfate proteoglycans (see entire document, including Abstract, pages 3041 and 3043). Also, Bassols et al. teach that TGF-β regulates proteoglycans in kidney and that TGFβ induces kidney fibroblast proliferation (see pages 3040-3041).

Given the teachings of Dasch et al. that TGF-β-specific antibodies could neutralize the effects of TGF-β in a several disorders; the one of ordinary skill in the art at the time the invention was made would have motivated to apply such TGF-β-specific antibodies in other disorders where TGF-β- played a role such as glomerulonephritis, as taught and indicated by Ruoslahti et al. and Bassols et al. From the teachings of the references, it was apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was prima facie obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

11. The non-statutory double patenting rejection, whether of the obvious-type or non-obvious-type, is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent. *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); *In re Van Omam*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); and *In re Goodman*, 29 USPQ2d 2010 (Fed. Cir. 1993).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321 (b) and (c) may be used to overcome an actual or provisional rejection based on a non-statutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.78 (d).

Effective January 1, 1994, a registered attorney or agent of record may sign a Terminal Disclaimer. A Terminal Disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

12. Claims 1-2, 5-7,10, and 13-15 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 21 and 35 of copending application USSN. 08/349,479.

Although the conflicting claims are not identical, they are not patentably distinct from each other because the pending claims of both the instant and copending applications are drawn to the same or nearly the same methods of treating glomerulonephritis with anti-TGF-β antibodies as they read on the elected invention.

It is noted that claim 35 of copending USSN 08/349,479 and claim 5 of the instant application read on treating adult respiratory distress syndrome (ARDS), which is a non-elected species in the instant application.

Therefore, the provisional double patenting rejection would be applicable to treating ARDS, given that treating ARDS with anti-TGF-β antibodies would anticipate the generic claims (claims 1-2, 5-7, 10, 13 and 15) of the instant application,

This is a *provisional* obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

13. No claim is allowed.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Phillip Gambel whose telephone number is (571) 272-0844. The examiner can normally be reached Monday through Thursday from 7:30 am to 6:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (571) 272-0841.

The fax number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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November 19, 2004